Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2162934	08/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Burbank Rehabilitation Center	5400 W 87th St, Burbank, IL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to perform proficiency testing (PT) using the laboratory's primary method of testing. Findings: 1. At 10:00 AM on August 13, 2019, the surveyor was escorted to the laboratory. 2. The surveyor observed that the following blood gas analyzers were in the laboratory: A. IRMA B. i-STAT 1 3. Review of PT records revealed that the laboratory tested PT samples using both analyzers. 4. The Technical Consultant stated that PT was performed on both the IRMA and i-STAT 1, because they wanted to ensure that both analyzers performed properly. She said the i-STAT 1 is their primary method of testing and that the IRMA would be their backup system. 5. The Technical Consultant confirmed the surveyor's findings.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an

	authorized person. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a written or electronic request for patient testing from an authorized person when it performed blood gas testing on patient specimens. Findings: 1. At 1:30 PM on August 13, 2019, the surveyor selected a patient tracer for review. The tracer included the following records: A. Patients' test result B. The Test Order C. Quality Control Records 2. The Test Order was not available for review. 3. In an interview with testing personnel, it was revealed that the laboratory did not keep the test orders in the laboratory. Testing Personnel told the surveyor that the orders are filed in the patients' physical charts, along with the test results. The test order could not be retreived from the patient's chart. She also stated that sometimes the laboratory is given verbal orders for blood gases. There was no documentation to show when verbal orders for blood gas testing are given. 4. At 1:40 on August 13, 2019, the Technical Consultant confirmed the surveyor's findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for blood gas testing performed. Findings: 1. The laboratory failed to have an all-inclusive comprehensive procedures manual. See D5403 2. The laboratory had 2 blood gas analyzers. The Technical Consultant recommended which analyzer the laboratory should use. However, the laboratory has not decided which analyzer is their primary instrument. See D5411 3. Before testing patients' specimens, the laboratory did not verify the performance characteristics established by the manufacturer for accuracy, precision, reportable range, and reference intervals. See D5421
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to have a comprehensive procedures manual that was all inclusive: Findings: 1. The procedures manual did not include requirements for specimen referral as described in 493.1242. 2. The procedures did not include reportable range for test results for the test system as established or verified in 493.1253. 3. The procedures did not include the laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. 4. The procedures did not include description of the course of action to take if a test system becomes inoperable. 5. At 11:00 AM on August 13, 2019, the Technical Consultant confirmed the surveyor's findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to select its primary test system for performing blood gas testing. Findings: 1. There were 2 blood gas analyzers in the laboratory, including an IRMA and i- STAT. 2. Proficiency Testing records show that the laboratory performed proficiency testing on both the IRMA and i- STAT 3. At 10:30 AM on August 13, 2019, in an interview with the Technical Consultant, the Technical Consultant stated that she recommended that the laboratory only use the i-STAT, but nothing has been decided.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on record review and interview, the laboratory failed to demonstrate that it can obtain performance specification comparable to those established by the manufacturer. Findings: 1. There were a total of 5 persons listed on the Laboratory Personnel Report (FORM CMS 209) submitted during the survey of August 13, 2019. 2. Personnel records show that 1 of 5 testing persons had documentation showing she was trained to perform testing using the i-STAT. Her i-STAT Operator Certificate was dated May 14, 2018. 3. There was no documentation to show that the laboratory verified the performance of the i-STAT for Accuracy, Precision, Reportable range of test results, and reference intervals. 4. The Technical Consultant stated that the laboratory switched to the i-STAT in January 2019. 5. At 1:30 PM on August 13, 2019 the surveyor selected a patient tracer from August 18, 2019. Blood gas test results were reported withoug the verification of the i-STAT's performance specification. 6. At 1:40 PM on August 13, 2019, the Technical Consultant confirmed the surveyor's findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure that quality of laboratory services provided. Findings: 1. Review of the laboratory's procedures revealed that there were Forms for documenting the following: A. i- STAT QC Log: Incoming QC B. Temperature and Humidity C. Patient Testing Log 2. Record review showed that testing personnel were using different logs than the ones in the back of the procedure manual. 3. The QC logs were not the ones from the procedure manual. 4. Temperature logs lacked documentation of the Humidity. 5. There was a lack of a patient testing log 7. There was no documenation to show that assessments of the laboratory's performance is monitored. 6. The Technical Consultant told the surveyor that she noticed the lack of specific records she was used to using in other labs she had worked in. Still, she failed to implement improvements in the way the laboratory operates. 7. At 1:40 PM on August 13, 2017, the Technical Consultant confirmed the surveyor's findings.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Consultant (TC) failed to be responsible for verification of the i-STAT analyzer for blood gas testing. Findings: 1.

	Personnel records show that at least 1 of 5 testing personnel were trained to perform blood gas testing on the i-STAT analyzer. 2. Proficiency testing (PT) records show that PT samples were tested with the i-STAT analyzer. 3. There was no documentation to demonstrate that the laboratory verified the i-STAT analyzer for precision and accuracy before it began performing patients' tests on the analyzer. 4. At 11:30 AM on August 13, 2019, the TC confirmed the surveyor's findings.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Consultant failed to be responsible for identifying training needs and assuring that everyone performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed. Findings: 1. There are a total of 5 persons listed on the Laboratory Personnel Report (FORM CMS 209) as moderate complexity testing personnel. 2. Laboratory records show that the laboratory adopted i-STAT procedures January 2, 2019. 3. There was no documentation to show that testing personnel were trained to perform blood gas testing with the i-STAT analyzer for 4 of 5 testing personnel. 4. Patients' test records show that patient's testing was performed by untrained testing personnel for 1 of 1 patient's test record reviewed. 5. At 1:PM on August 13, 2019, the Technical Consultant confirmed the surveyor's findings